AND BRIEFS

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In The
Supreme Court of the United States

SANDOZ INC.,

Petitioner,

v.

AMGEN INC., *et al.*,

Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF OF AMICI CURIAE PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION, NATIONAL ASSOCIATION OF CHAIN DRUG STORES, AND HEALTHCARE SUPPLY CHAIN ASSOCIATION IN SUPPORT OF PETITIONER

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This brief is submitted on behalf of the Pharmaceutical Care Management Association, National Association of Chain Drug Stores, and Healthcare Supply Chain Association, as *amici curiae* in support of Petitioner Sandoz Inc.[1]

INTEREST OF THE AMICI CURIAE

Amici curiae collectively represent many of the organizations involved in getting prescription medicines from manufacturers to patients, including organizations and entities that purchase prescription medicines on behalf of patients, develop and maintain drug formularies, process insurance claims, negotiate contracts for prescription drugs with pharmacies and drug manufacturers, dispense prescription medicines to patients, and aid patients in taking their medicines correctly and safely.

The Healthcare Supply Chain Association (HSCA) is a non-profit association that represents fourteen group purchasing organizations (GPOs) for pharmaceuticals and other products and services used by healthcare providers. GPOs negotiate contracts with healthcare manufacturers and distributors on behalf of group members, harnessing their members' collective purchasing power. They also help group members manage complex purchasing systems to improve efficiency and reduce errors. Group members include for-profit and non-

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[1] The parties have consented in writing to the filing of this *amicus curiae* brief. No counsel for any party authored this brief in whole or in part, and no person or entity, other than amici curiae or their counsel, made a monetary contribution intended to fund the preparation or submission of this brief.

profit corporations, associations, multi-hospital systems, clinics, surgery centers, nursing homes, and healthcare provider alliances. As of 2015, over ninety-eight percent of all non-profit, non-governmental hospitals participate in at least one GPO. On average, seventy-two percent of all hospital purchases are made through GPO contracts. HSCA works to facilitate an open dialogue between GPOs regarding best procurement practices, and works on behalf of GPOs to ensure fair and efficient procurement practices in an open and competitive market within the health industry.

The Pharmaceutical Care Management Association is a non-profit national trade association representing America's pharmacy benefit managers (PBMs). PBMs administer prescription drug plans for more than 266 million Americans who have health insurance from a variety of sponsors including: commercial health plans, self-insured employer plans, union plans, Medicare Part D plans, the Federal Employees Health Benefits Program, state government employee plans, managed Medicaid plans, and others. PBMs also provide services to plan sponsors which can include formulary development and maintenance, as well as prospective and retrospective drug utilization reviews. Most sophisticated purchasers of healthcare products in the United States utilize the services of a PBM.

The National Association of Chain Drug Stores (NACDS) is a 501(c)(6) non-profit trade association. Its mission includes advancing the interests and objectives of chain community pharmacies, such as supporting their role as

healthcare providers. NACDS membership consists of chain community pharmacy companies – including traditional drug stores, supermarkets, and mass merchants with pharmacies – from regional chains with four pharmacies to national companies. NACDS has more than 100 members which, collectively, operate 40,000 pharmacies in the United States and employ 178,000 pharmacists. NACDS members fill more than three billion prescriptions annually, including prescriptions for biologics, and aid patients in taking their medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability.

As trade associations representing industry actors involved in the distribution of prescription medicines and care of patients nationwide, *amici* have a significant interest in, and a unique perspective on, the important issue of delay to market of biosimilars raised in this case. If it stands, the U.S. Court of Appeals for the Federal Circuit's decision will deny patients access to biosimilars licensed by the Food and Drug Administration (FDA) for 180 days (approximately six months), without regard to whether a legitimate patent claim actually exists regarding the biosimilar in question. Each *amicus* represents members with a strong interest in ensuring that patients in the United States receive the most cost-efficient and effective drugs prescribed without undue delay. *Amici* believe that their perspectives will assist the Court in resolving this case, in accordance with Sup. Ct. R. 37.1.

SUMMARY OF THE ARGUMENT

In passing the Biologics Price Competition and Innovation Act (BPCIA), Congress struck a balance between medical innovation and consumer access. The Federal Circuit has misinterpreted the text of the BPCIA, at 42 U.S.C. § 262(*l*)(8)(A), and in so doing has conferred an unintended benefit on innovator drug sponsors – 180 days of additional market exclusivity – at the expense of the significant consumer interest in access to effective biologics. *Amici* urge the Court to reject the Federal Circuit's interpretation of § 262(*l*)(8)(A).

The importance of biosimilars to the public interest can hardly be overstated. Biologics are some of the most promising medicines available today, and they are also some of the most expensive. They represent a significant and growing percentage of total prescription drug costs for drug purchasers and payers throughout the country, both public and private. The high cost of these products is also experienced directly by patients in the form of co-insurance or copays to cover some portion of the drug price, or in the form of rising insurance premiums. For many individual patients, the costs are untenable.

Amici are concerned that six additional months without biosimilar competition will place a significant burden on payers, purchasers, and pharmacies, and will negatively affect patients' access to treatment and affordable health care. The market introduction of similar or interchangeable products can be expected to drive average prices down, thereby improving patient access. Any delay

to market competition will necessarily delay that effect. For patients who take a medicine that may cost tens of thousands of dollars per year, and for payers and drug purchasers who bear much of that cost, six months of lower prices would make a meaningful difference.

In light of the sacrifice it represents to the public's interest in effective, lower-cost medicines, the Federal Circuit's decision is particularly objectionable because it is not required – or even supported – by the language of the statute or its purpose. The text of 42 U.S.C. § 262(*l*)(8)(A) requires only that notice be provided "not later than 180 days before the date of the first commercial marketing." The Federal Circuit created an implied requirement that notice be provided only *after* FDA has licensed the biosimilar at issue. But this reading conflicts with the plain language of § 262(*l*)(8), which refers to the "applicant" both in describing (1) the entity required to give 180-day notice, and (2) the entity against whom a reference biologic sponsor must seek an injunction. In plain English, as well as in the statute's specific parlance, the term "applicant" describes an entity that has filed a Biologics License Application (BLA) *before* that BLA has been approved by FDA. Once FDA has approved the BLA, the same entity is called the "holder" or "sponsor" of the BLA, not an "applicant."

Nor does the statutory context support the Federal Circuit's interpretation of 42 U.S.C. § 262(*l*)(8)(A). The BPCIA sets forth a comprehensive procedure for patent litigation that allows the reference biologic sponsor to defend its patent rights effectively and efficiently. Considering that scheme

as a whole, the six months additional exclusivity inserted by the Federal Circuit is unnecessary to safeguard biologic sponsors' rights under the BPCIA and patent law.

ARGUMENT

I. The Circuit Court's Interpretation of 42 U.S.C. § 262(*l*)(8)(A) Conflicts with Congress' Intent and Is Not in the Public Interest.

The Federal Circuit's reading of 42 U.S.C. § 262(*l*)(8)(A) extends exclusivity for reference biologics by approximately six months, to *twelve-and-a-half* years. An additional six months of biologics exclusivity imposes significant costs throughout the drug supply chain that ultimately harm consumer interests and are not necessary to safeguard patent rights and encourage innovation. This result conflicts with Congress' intent in passing the BPCIA. *See* BPCIA, Pub. L. No. 111-148, § 7001(b), 124 Stat. 119, 804 (2010) ("It is the sense of the Senate that a biosimilars pathway *balancing innovation and consumer interests* should be established." (emphasis supplied)).

As stated above, *amici* represent actors throughout the pharmaceutical supply chain that have a common purpose of ensuring patient access to innovative and effective treatments at the lowest feasible cost. Absent competition, biologics represent a substantial and increasing portion of prescription drug costs borne by *amici*'s members organizations, and the patients they serve. Even a six-month delay in competition for these products can be expected to

impose significant costs on *amici* members and will negatively affect consumer access.

a. Six Months Additional Exclusivity Will Impose Significant Costs on Industry and Patients.

Biologics are some of the most costly drugs on the market. *See* Fed. Trade Comm'n, Transcript of Follow-On Biologics Workshop at 54 (Feb. 4, 2014), https://www.ftc.gov/system/files/documents/public_events/171301/140204biologicstranscript.pdf (Lee Purvis, AARP) ("The average annual cost of a branded biologic is estimated to be roughly 35,000 dollars right now. However, annual costs can range anywhere from 25,000 to 200,000 dollars or more."). These high prices, in combination with an increase in the number of biologics and number of indications for current biologicals, translate to a rapid growth in spending on biologics throughout the country. *See id.* at 53-54. In fact, spending on biologics increased from $67 billion in 2010 to $92 billion in 2013. *See* Alex Brill, *The Economic Viability of a U.S. Biosimilars Industry*, Matrix Global Advisors, 4 (Feb. 2015). Biologics accounted for thirty-three percent of all drug spending in 2015 for one public payer, the Ohio Public Employees Retirement System (OPERS). *See* Anna Rose Welch, *The Healthcare Purchaser's Role in Biosimilar Uptake*, Biosimilar Development (Oct. 18, 2016), https://www.biosimilardevelopment.com/doc/the-healthcare-purchaser-s-role-in-biosimilar-uptake-0001. The same public payer estimated that its percentage of drug spending attributed to biologics could rise to fifty percent by 2018. *Id.* On average, biologics are twenty-two times more expensive than traditional

(small molecule) drugs, and prices continue to increase. *See* Leigh Purvis, *A Sense of Déjà vu: The Debate Surrounding State Biosimilar Substitution Laws*, AARP Public Policy Institute, 1 (2014), www.aarp.org/content/dam/aarp/research/public_policy_institute/health/2014/the-debate-surrounding-state-biosimilar-substitution-laws-AARP-ppi-health.pdf.

Prior to passage of the BPCIA, the Congressional Budget Office estimated that the biosimilars pathway would reduce direct spending by the federal government by $5.9 billion over the 2009-2018 period, and would reduce total expenditures on biologics by $25 billion. *See* Cong. Budget Office, *Cost Estimate: Biologics Price Competition and Innovation Act of 2007*, 1 (June 25, 2008).[2] The same public payer mentioned above, the OPERS, estimated that it could save approximately $134 million over ten years with competition for biologics. *See* OPERS, Biosimilars Stakeholder Panel Presentation by Brian Lehman, Manager of Pharmacy and Benefits, 6, http://www.gphaonline.org/media/wysiwyg/Meetings/BIO_2016/Brian_Lehman.pdf (last visited Feb. 15, 2017). Assuming that six months additional exclusivity for every biological product will proportionately decrease expected savings from biosimilar competition within the same time periods, it will cost

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[2] Other industry analyses have estimated potential savings from biosimilars of between $1 billion and $108 billion over an approximately ten-year period. *See* Andrew W. Mulcahy et al., *The Cost Savings Potential of Biosimilar Drugs in the United States*, RAND Corp., 6 (2014). Even using the most conservative of these estimates—$1 billion—six months of additional exclusivity for each biosimilar translates to $50 million in lost savings for the U.S. healthcare market.

the federal government approximately $327.8 million between 2009-2018, and the U.S. healthcare market as a whole $1.4 billion. A single public payer, the OPERS, will lose approximately $6.7 million over ten years.

b. Six Months Additional Exclusivity Will Negatively Affect Patient Access to Biologics.

The high cost of biologics discussed above directly affects patients. *Amici* are concerned that patients' access to biologics in the six months following FDA licensure of a biosimilar will suffer as a result of the Federal Circuit's decision. *Amici* are also concerned that six months of additional costs associated with market exclusivity for reference biologics will increase the insurance premiums paid by all consumers, thereby negatively affecting those consumers' ability to afford health care.

A patient with rheumatoid arthritis may consume $30,000 to $40,000 worth of drug per year. *See* Fed. Trade Comm'n, Transcript of Follow-On Biologics Workshop at 267-68 (Feb. 4, 2014) (Harry Travis, Aetna); *see also* Harry Travis, Aetna, Presentation at Fed. Trade Comm'n Follow-On Biologics Workshop: Private Payor Perspective on Growth of Specialty Medicines and Naming (Feb. 4, 2014), https://www.ftc.gov/system/files/documents/public_events/FollowOn%20Biologics%20Workshop%3A%20Impact%20of%20Recent%20Legislative%20and%20Regulatory%20Naming%20Proposals%20on%20Competition/travis.pdf. For such expensive drugs, even patients with drug benefits pay a significant percentage of the drug cost. *See, e.g.*, J. Yazdany et

al., *Coverage for High-Cost Specialty Drugs for Rheumatoid Arthritis in Medicare Part D*, 67 Arthritis Rheumatol. 1474 (2015) (reporting that Medicare beneficiaries pay on average 29.6% of the cost for biologics to treat rheumatoid arthritis). Manufacturer patient assistant programs often exclude patients whose income rises above a certain level, and even patients that might otherwise qualify are not always aware that they exist. *See* Joseph Walker, *Patients Struggle With High Drug Prices*, Wall Street J. (Dec. 31, 2015), https://www.wsj.com/articles/patients-struggle-with-high-drug-prices-1451557981. Medicare patients are prohibited from using some forms of manufacturer patient assistance programs. *Id.* (estimating that a Medicare patient with rheumatoid arthritis would pay nearly $5,000 out-of-pocket to treat the disease with a biologic in 2016). Faced with thousands of dollars in out-of-pocket costs for an effective biologic, patients are incentivized to choose less costly alternatives or forgo treatment altogether.

Introducing competition for a biologic provides a lower-cost alternative. *See* Andrew W. Mulcahy et al., *The Cost Savings Potential of Biosimilar Drugs in the United States*, RAND Corp., 3-4 (2014) ("Competition is the final and most important driver of cost-savings [for biologics]."). Even where the resulting price reductions are modest—10%, for example—the annual difference between $30,000 and $27,000 is not insignificant to consumers paying a significant portion of the cost of a drug out of pocket, and can affect the choice of therapy.

Lower cost options for biologics can also increase patient access to biologics indirectly by

affecting treatment guidelines for a particular condition. Treatment recommendations and guidelines take into account the cost of various treatment options because, as discussed above, the cost is expected to influence patients' decision-making. *See, e.g.*, Jasvinder A. Singh et al., *2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis*, Arthritis Care & Research, 4, 6, 7, 8, 10 (2016). The high cost of a particular therapy can contribute to its being recommended for use only in more advanced stages of a disease, or as a second- or third-line, rather than first-line, treatment. *See, e.g.*, *id.* at 10 ("The recommendation is **strong** despite the low quality of evidence because DMARD monotherapy [as compared to a TNFi biologic] is available as a less costly first-line therapy that has an extensive safety record . . . ."). Conversely, lowered costs for a biologic may result in more patients being prescribed that therapy at an earlier stage of their disease, or increase the number of patients who are prescribed the biologic as a first-line therapy. *See, e.g.*, Murray Aitken, *Delivering on the Potential of Biosimilar Medicines: The Role of Functioning Competitive Markets*, IMS Inst. for Healthcare Informatics, 8-9 (Mar. 2016), http://www. imshealth.com/files/webIMSH%20Institute/Healthcare%20Briefs/Documents/IMS_Institute_Biosimilar_Brief_March_2016.pdf (citing the market experience of filgrastim in the United Kingdom, where the availability of a biosimilar changed official treatment guidelines, resulting in a greater number of patients being treated with filgrastim).

Even patients who do not require treatment with a biologic are negatively affected by the high

cost of biologics, because high prices for biologics cause the cost of health insurance to rise for all consumers. *See* Fed Trade Comm'n, Transcript of Follow-On Biologics Workshop at 265-66 (Feb. 4, 2014) (Harry Travis, Aetna). Conversely, lowered costs for biologics reduce the pressure on payers and purchasers, potentially creating room for procurement and coverage of additional therapies for patients.

II. The Plain Language of 42 U.S.C. § 262(*l*)(8)(A) Requires Notice Prior to Commercial Marketing, and Nothing More.

Contrary to the Federal Circuit's majority opinion, the plain language of 42 U.S.C. § 262(*l*)(8)(A) does not require the additional six months of exclusivity discussed above. In fact, the plain language of § 262(*l*)(8)(A) requires only that applicants provide notice 180 days before commercial marketing, nothing more.

Section 262(*l*)(8)(A) states:

> "The subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)."

Amici agree that the requirement to provide notice 180 days before launch is clear. However, the Federal Circuit determined that FDA licensure must occur *before* this notice is given; a requirement that

does not appear in the text, is not necessitated by the statutory context, and does not serve any rational legislative purpose.

The canons of statutory construction require courts to "presume that a legislature says in a statute what it means and means in a statute what it says there." *Conn. Nat'l Bank v. Germain*, 503 U.S. 249, 253-54 (1992). Contrary to the Federal Circuit's majority opinion, the plain language here does not limit how early notice may be sent. Rather, § 262(*l*)(8)(A) is explicitly limited to the *latest* time notice may be sent.

In fact, the language used in § 262(*l*)(8)(A) is consistent with the district court's interpretation that notice may be provided prior to licensing. *See Amgen Inc. v. Sandoz Inc.*, No. 14-cv-04741, 2015 U.S. Dist. LEXIS 34537, at *21-25 (N.D. Cal. Mar. 19, 2015). The text of § 262(*l*)(8)(A) states that a BLA "*applicant*" is to provide notice at least 180 days prior to marketing. A post-licensure sponsor is not an "applicant," but is a sponsor, or holder, of an approved application. If Congress intended the holder of an approved application to provide notice and wait 180 days before marketing, it would have expressly used the term "holder of an approved application" rather than "applicant." *See, e.g.*, 42 U.S.C. § 262(m)(3); *see also* 21 U.S.C. § 355(b)(3)(C)(ii) ("holder of the approved application"). Congress' use of the term "applicant" is dispositive. The statute must be read such that the *applicant* may give notice, and this can be achieved only if notice occurs prior to licensure.

In light of Congress' use of the term "applicant," the phrase "licensed under subsection (k)," 42 U.S.C. § 262(*l*)(8)(A), is more appropriately read to refer to the concept of "first commercial marketing," rather than that of notice. The phrase "biological product licensed under subsection (k)," *id.*, merely identifies the relevant product, which must be licensed upon first commercial marketing.

The Federal Circuit majority opinion reasons that Congress must have intended licensure as the start of a notice period because it otherwise would have used the phrase "the biological product that is the subject of the application" as it did elsewhere in the BPCIA. *Id.* § 262(*l*)(1)(D); *Amgen, Inc. v. Sandoz, Inc.*, 794 F.3d 1347, 1358 (Fed. Cir. 2015). However, the wording that the Federal Circuit's reasoning suggests—which would read "notice . . . not later than 180 days before the first commercial marketing of the biological product that is the subject of the application"—implies potential commercial marketing of an as-yet-unlicensed product; an absurd idea. Furthermore, the same argument regarding the phrasing Congress *should* have used can be made to discredit the Court's interpretation: had Congress intended the 180-day period in § 262(*l*)(8)(A) to begin only after FDA licensure, it could have included a provision explicitly prohibiting notice until that time. Thus, the Court's suggested alternative phrasing holds little weight, particularly when compared to the clear language that Congress did choose.

Finally, the Federal Circuit's interpretation of § 262(*l*)(8)(A)'s notice provision must be rejected

because it would render § 262(*l*)(8)(B) superfluous. *See Hibbs v. Winn*, 542 U.S. 88, 92 (2004) ("[T]he rule against superfluities instructs courts to interpret a statute to effectuate all its provisions, so that no part is rendered superfluous."). Section 262(*l*)(8)(B) requires a sponsor to affirmatively "*seek* a preliminary injunction prohibiting the . . . *applicant*" from marketing the biosimilar product based on its 180-day notice. 42 U.S.C. § 262(*l*)(8)(B) (emphasis supplied). The term "applicant," once again, indicates that the injunction in question would be sought in response to 180-day notice *before* an application is licensed by FDA. Moreover, if the Federal Circuit's interpretation of § 262(*l*)(8)(A) were correct, there would be no need to seek an injunction in addition to the automatic 180-day stay on marketing.

III. The Federal Circuit's Interpretation of 42 U.S.C. § 262(*l*)(8)(A) is Inconsistent With the Larger Context of § 262(*l*) and the BPCIA.

The Federal Circuit's determination that notice under § 262(*l*)(8)(A) must be given post-licensure also ignores the larger context of the notice requirement. Section 262(*l*)(8)(A) cannot be read in a vacuum. "It is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme." *Davis v. Mich. Dep't of Treasury*, 489 U.S. 803, 809 (1989). The Federal Circuit's majority opinion misinterprets the statutory scheme, and the substance of the remaining statutory provisions.

According to the Federal Circuit majority opinion, notice after licensure is the only logical reading of § 262(*l*)(8)(A), because it allows reference product sponsors to understand the scope of the approved license and presents a "fully crystallized" controversy to determine whether to seek a preliminary injunction. *See Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1358 (Fed. Cir. 2015). However, the Federal Circuit places too much emphasis on the notice provision, and not enough on the pre-notice litigation scheme.

Section 262(*l*), as a whole, sets out a procedure for the reference product sponsor to enforce its patent rights with respect to a biosimilar application. Specifically, § 262(*l*) details an information exchange leading up to a patent infringement suit expected to occur while the licensing application is under review. If the parties engage in the information exchange, the statutory procedure allows for the product sponsor to receive a copy of the biosimilar application and exchange patent information with the applicant, ultimately leading to a narrower patent infringement suit. Alternatively, the statute allows for commencement of a patent infringement action shortly following FDA's acceptance of the biosimilar licensing application for review.[3] With the exchange of patent information, opportunity for patent resolution negotiations, and availability of an infringement action outlined in § 262(*l*), the statute provides

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[3] The mere filing of the biosimilar application is an act of patent infringement and grounds for litigation prior to licensure under 35 U.S.C. § 271(e)(2)(C)(ii).

ample opportunity for a reference product sponsor to enforce its patent rights.

Section 262(*l*)(8)(A) exists as a safeguard to ensure that a reference product sponsor has enough time to seek an injunction if needed, and not as an additional period in which to make patent litigation decisions. Giving notice in excess of 180 days does not interfere with the sponsor's ability to seek an injunction, and in fact gives the sponsor *more* time in which to prepare to file, or file, for an injunction in advance of FDA approval of a biosimilar (a public act). If, on the other hand, an applicant guesses wrong regarding its expected FDA approval date and provides notice *less* than 180 days before that date, it is prohibited from entry until 180 days from notice has elapsed. There is, therefore, little logic to prohibiting notice until licensure; as long as notice is given at least 180 days prior to commercial marketing, the purpose of the statutory requirement is fulfilled.

The BPCIA also provides consequences for failure to provide timely notice under § 262(*l*)(8). Specifically, § 262(*l*)(9) permits the reference product sponsor to bring a declaratory infringement action against an applicant who fails to provide the required 180-day notice. The Federal Circuit's reading, however, imposes additional consequences even on those who comply with § 262(*l*) in full, in the form of a mandatory automatic 180-day stay on marketing.

This automatic stay, which occurs regardless of whether the biosimilar applicant has followed

each statutory requirement to the letter, and regardless of the merits of the patent claims at issue, is a windfall for reference product sponsors that serves no rational purpose for the protection of patent rights. This outcome is inconsistent with a statutory scheme designed to dispense quickly with patent litigation, and speed biosimilars to market.

CONCLUSION

For the reasons articulated above, *amici* respectfully request that the Court reverse the decision of the court below with respect to its interpretation of 42 U.S.C. § 262(*l*)(8)(A).

Respectfully submitted,

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